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09/516,052	03/01/2000	John Harada	02307O-077630US	3907

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Townsend and Townsend and Crew
Two Embarcadero Center 8th Floor
San Francisco, CA 94111-3834

EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	19

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/516,052	Applicant(s) HARADA ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) *4-8,10-20,23-27,30-34,37-38,40-41,44-46,50-53,* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9,21,22,28,29,35,36,39,42,43,47-49,54,55,58,63 and 69-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Amendment filed May 16, 2002, paper no.16, has been entered.

Claims 1, 21, 35, 42, 47, 54 and 55 are newly amended.

Claims 70-73 are newly added.

Claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69-73 are pending.

Claims 4-8, 10-20, 23-27, 30-34, 37-38, 40-41, 44-46, 50-53, 56-57, 59-62 and 64-68 are withdrawn from consideration as being directed to nonelected inventions.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed May 10, 2002, Paper No. 18, is attached to the instant Office action.

Claim Objections

The objection to claims 35, 42, 54 and 55 is withdrawn in light of the amendment of claims 35, 42, 54 and 55.

Claim Rejections - 35 USC § 112

Claims 21, 22, 28, 29 and 39 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed December 4, 2001.

Applicants' arguments filed December 4, 2001, have been fully considered but they are not persuasive.

Applicants argue that the present specification provides ample written description for the pending claims, precisely as required by *University of California v. Eli Lilly & Co.* Applicants argue that the claim language, directed to polynucleotides that encode polypeptides comprising a subsequence at least 80% identical to the B domain of SEQ ID NO:2, wherein the polypeptide modulates embryo development when expressed in plants, defines a physical and a structural property of the invention (reply page 5).

The Examiner maintains that the mere recitation of a physical and a structural property of the invention does not satisfy the written description requirement. The Examiner maintains that to satisfy the written description requirement, the specification must describe the structural features of the claimed polynucleotides that are correlated with the physical feature of modulating embryo development, because not all polynucleotides encoding LEC1 polypeptides comprising a subsequence at least 80% identical to the B domain of SEQ ID NO:2 encode a polypeptide that will modulate embryo development when expressed in plants. The Examiner maintains that the specification must describe the structural features of the claimed polynucleotides in such a way that one skilled in the art would have a basis for distinguishing polynucleotides encoding LEC1 polypeptides that will modulate embryo development when expressed in plants from polynucleotides encoding LEC1 polypeptides that will not modulate embryo development when expressed in plants.

Claims 1-3, 9, 35-36, 42-43, 47, 54-55, 58, 63 and 69-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotide sequences encoding a LEC 1 polypeptide comprising a subsequence at least 80% identical to the B domain of SEQ ID NO:2, wherein the polynucleotide modulates embryo development when expressed in a plant. The claims are also drawn to methods of modulating embryo development by introducing into a plant a heterologous LEC1 polynucleotide encoding a LEC1 polypeptide comprising a subsequence at least 80% identical to the B domain of SEQ ID NO:2.

However, the specification does not set forth what specific structural or physical features are required in the claimed polynucleotides. The specification only describes the sequence of three polynucleotides, the *Arabidopsis* LEC1 gene (SEQ ID NO:1), the *Arabidopsis* LEC1-Like gene(SEQ ID NO:19) which was initially identified in the Arabidopsis BAC clone MNJ7 by a BLAST search of an Arabidopsis database (page 40 line 28 to page 40 line2), and the *Phaseolus coccineus* LEC1-Like gene (SEQ ID NO:21). The specification also discloses that the polynucleotides of SEQ ID NO:1 and SEQ ID NO:19 modulate embryo development when expressed in a plant, as evidenced by their ability to complement a *lec1* mutation (Example 2 pages 38-40 and Example 4 pages 40-42). The specification does not describe any "heterologous LEC1 polynucleotide" that functions to modulate embryo development when expressed in a plant. The specification also does not adequately describe "LEC1 polynucleotides" that function to modulate embryo development when expressed in a plant. While the specification defines a

LEC1 polynucleotide as a nucleic acid sequence comprising or consisting of a coding region of about 100 to about 900 nucleotides, sometimes from about 300 to about 630 nucleotides, which hybridizes to SEQ ID NO:1 under stringent conditions, or which hybridizes under low stringency conditions to nucleic acid probes having a sequence from position 1 to 81 in SEQ ID NO:1 or from position 355 to 627 in SEQ ID NO:1 (specification page 8), the specification describes only two nucleotide sequences that fall within this structural definition that function to modulate embryo development when expressed in a plant, SEQ ID NOS:1 and 19. The disclosure of two nucleotide sequences that function to modulate embryo development when expressed in a plant is not sufficient to describe "LEC1 polynucleotides". Furthermore, the specification does not adequately describe "LEC 1 polypeptides" that function to modulate embryo development when expressed in a plant. While the specification defines a LEC1 polypeptide as a sequence of about 50 to about 210, sometimes 100 to 150, amino acids encoded by a LEC1 polynucleotide (specification page 8), the specification describes only two polypeptides that fall within this structural definition that function to modulate embryo development when expressed in a plant, SEQ ID NOS:2 and 20. The disclosure of two polypeptides that function to modulate embryo development when expressed in a plant is not sufficient to describe "LEC1 polypeptides". Additionally, the specification does not adequately describe "LEC1 polypeptides comprising a subsequence at least 80% identical to the B domain of SEQ ID NO:2" that function to modulate embryo development when expressed in a plant. The specification describes only two polypeptides that fall within this structural definition that function to modulate embryo development when expressed in a plant, SEQ ID NO:2, which has a subsequence 100% identical to the B domain of SEQ ID NO:2, and SEQ ID NO:20, which Applicants have indicated has a

subsequence 83.3% identical to the B domain of SEQ ID NO:2. The disclosure of one polypeptide having a subsequence 100% identical to the B domain of SEQ ID NO:2, and one polypeptide having a subsequence 83.3% identical to the B domain of SEQ ID NO:2, each of which functions to modulate embryo development when expressed in a plant, is not sufficient to describe "LEC1 polypeptides comprising a subsequence at least 80% identical to the B domain of SEQ ID NO:2" that function to modulate embryo development when expressed in a plant.

Claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69 remain rejected, and newly added claims 70-73 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a LEC 1 polypeptide comprising SEQ ID NO:2, does not reasonably provide enablement for an isolated nucleic acid encoding a LEC 1 polypeptide comprising a subsequence at least 80% identical to the B domain of SEQ ID NO:2, for the reasons of record set forth in the office action mailed December 4, 2001.

Applicants' arguments filed December 4, 2001, have been fully considered but they are not persuasive.

Applicants argue that the specification provides methods of constructing and testing the polynucleotides of the invention for function, and that the specification also provides a working example demonstrating that the L1L protein, which has approximately 80% identity with LEC1 (SEQ ID NO:2), can act to complement a *lec1* mutation, demonstrating that sequences encoding a polypeptide at least 80% identical to SEQ ID NO:2 can function to modulate embryo development. Applicants also point to the declaration of John J. Harada submitted under 37

C.F.R. 1.132 illustrating that polypeptides comprising a subsequence about 68% identical to the B domain of SEQ ID NO:2 are functional. (reply page 6). Applicants argue that the specification describes the *Arabidopsis* LEC1 polypeptide and other related sequences and their effect on embryo development, and that those of ordinary skill in the art could have readily identified the functional polypeptides within the scope of the claims by employing the methods described in the specification. (reply pages 6-7).

Applicants also argue that The L1L polypeptide provides further evidence that polypeptides at least 80% identical to SEQ ID NO:2 function to modulate embryo development, because, as disclosed on pages 41-42 of the specification, L1L complements *lec1* mutant plants. Applicants further point to the Harada declaration, which presents an alignment of LEC1 and L1L, showing that LEC1 and L1L are 83.3% identical within the B domain of SEQ ID NO:2, and demonstrating that the L1L polypeptide modulates embryo development when introduced into plants. Applicants argue that the results demonstrate that polypeptides comprising a sequence at least 80% identical to the B domain of SEQ ID NO:2 modulate embryo development in plants. (reply page 7).

Applicants argue that the Harada declaration also demonstrates that a polypeptide with only 68% sequence identity to the B domain of SEQ ID NO:2, K28D At4g14540, can modulate embryo development in plants. Applicants argue that the present claims are well within the scope of active variants of the LEC1 sequence, since a sequence having 68% sequence identity to the B domain of SEQ ID NO:2 is functional (reply page 8).

The Examiner acknowledges the working example demonstrating that the L1L protein, which has 83.3% identity with LEC1 (SEQ ID NO:2), can act to complement a *lec1* mutation,

and the declaration submitted under 37 C.F.R. 1.132 illustrating that a polypeptide with 68% identity to the B domain of SEQ ID NO:2, K28D At4g14540, can act to complement a *lec1* mutation, but the Examiner does not agree that these two examples enable the full scope of the claimed invention. The Examiner further maintains that the claims are not drawn to methods of constructing and testing the polynucleotides of the invention for function, but to the polynucleotides themselves. Accordingly, the Examiner maintains that the specification does not provide sufficient guidance for one skilled in the art to determine, without undue experimentation, which polynucleotides could reasonably be expected to encode a LEC1 polypeptide comprising a subsequence at least 80% identical to the B domain of SEQ ID NO:2 that will modulate embryo development when expressed in plants, because the specification discloses only two such polynucleotides, the polynucleotide of SEQ ID NO:1 encoding the *Arabidopsis* LEC1 polypeptide, and the polynucleotide of SEQ ID NO:19 encoding the *Arabidopsis* L1L polypeptide. The Examiner maintains that the undue experimentation required to practice the claimed invention lies in the selecting of the polynucleotides encoding a LEC1 polypeptide that will modulate embryo development when expressed in plants, not in the methods of constructing and testing the polynucleotides of the invention for function. The claims encompass an enormous number of sequences, given that the specification defines a LEC1 polypeptide as a sequence of about 50 to about 210, sometimes 100 to 150, amino acids encoded by a LEC1 polynucleotide, which is defined as a nucleic acid sequence comprising or consisting of a coding region of about 100 to about 900 nucleotides, sometimes from about 300 to about 630 nucleotides, which hybridizes to SEQ ID NO:1 under stringent conditions, or which hybridizes under low stringency conditions to nucleic acid probes having a sequence from

position 1 to 81 in SEQ ID NO:1 or from position 355 to 627 in SEQ ID NO:1 (specification page 8). Given the large number of sequences encompassed by the claims, and the lack of guidance for selecting sequences that encode a LEC1 polypeptide that will modulate embryo development when expressed in a plant, it would require undue experimentation for one skilled in the art to select sequences that will modulate embryo development.

The rejection of claim 21 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of the vernacular term "clone MNJ7" is withdrawn in light of the amendment of claim 21.

The rejection of claims 47, 54 and 55 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "modulating" and "modulated" is withdrawn in light of the amendment of claim 47.

Claims 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "modulating transcription". There is insufficient antecedent basis for this limitation in claim 47, from which claims 54 and 55 depend.

Claim Rejections - 35 USC § 102

Claims 21, 22, 28 and 29 remain rejected under 35 U.S.C. 102(b) as being anticipated by either of Lotan et al. (GenEmbl Accession AF036684, 02 July 1998) or Feng et al. (GenBank Accession AQ251011, 07 October 1998), for the reasons of record set forth in the office action mailed December 4, 2001.

Claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69 remain rejected, and newly added claims 70-73 are rejected, under 35 U.S.C. 102(b) as being anticipated by Lotan et al. (Cell, Vol. 93, pages 1195-1205, June 26, 1998), for the reasons of record set forth in the office action mailed December 4, 2001.

Applicants' arguments filed December 4, 2001, have been fully considered but they are not persuasive.

Applicants argue that the references are not anticipatory because the claimed subject matter claims priority to at least U.S. serial number 09/103,478, filed June 24, 1998, now U.S. Patent No. 6,235,975, which discloses the sequence of the *Arabidopsis* LEC1 gene. (reply page 10).

The Examiner maintains that the cited references do anticipate the claimed invention because the claimed subject matter is not entitled to claim priority to at least U.S. serial number 09/103,478. U.S. serial number 09/103,478 discloses the sequence of the *Arabidopsis* LEC1 gene and the polypeptide it encodes (SEQ ID NO:2), but U.S. serial number 09/103,478 does not disclose isolated polynucleotides encoding LEC1 polypeptides comprising a subsequence at least 80% identical to the B domain of SEQ ID NO:2 that will modulate embryo development when expressed in plants.

Double Patenting

Claims 1-3, 9, 21-22, 28-29, 35-36, 39, 42-43, 47-49, 54-55, 58, 63 and 69 remain rejected, and newly added claims 70-73 are rejected, under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No.

6,235,975 (May 22, 2001), for the reasons of record set forth in the office action mailed December 4, 2001.

Applicants' arguments filed December 4, 2001, have been fully considered but they are not persuasive.

The Examiner acknowledges Applicants' statement that Applicants will consider providing a terminal disclaimer after the Examiner indicates that the claimed subject matter is otherwise available. Providing a terminal disclaimer would overcome the rejection.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
July 27, 2002

ELIZABETH F. MCELWAIN
PRIMARY EXAMINER
GROUP 1600